Bioterror and Pandemic Preparedness Protection Act

Section-by-Section

Section 1

The Act is called the "Bioterror and Pandemic Preparedness Protection Act".

Section 2

Amends the Public Health Service Act by inserting section 319F-3.

Sec.319A-3. Liability Protections for Pandemics, Epidemics and Security Countermeasures

(1) Federal Cause of Action—

- Provides a Federal cause of action for all claims relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, administration, and use (hereinafter identified as "use") of a security countermeasure or qualified pandemic or epidemic product.
- The action is against the United States for products that are purchased by the United States or identified in a declaration of a public health emergency under 319A of the PHSA.
- Sole and exclusive jurisdiction is in the US District Court for the District of Columbia.

(2) Affirmative Defense—

- Creates a rebuttable presumption that the Federal Government is immune from liability relating to the use of a security countermeasure or a qualified pandemic or epidemic product-
    - That has been procured for the National Strategic Stockpile or procured by the government whether sold to the government or nongovernmental sources.
    - Used in preparation for, in defense against, or in response or recovery to an actual or potential public health emergency under section 319A of the PHSA.

- The presumption can be rebutted by-
    - A determination by the Secretary that clear and convincing evidence demonstrate that the manufacturer, distributor, dispenser, or health care provider intentionally or with willful disregard violated a provision of the FFDCA or the PHSA, which cause the product to present a significant risk to health and proximately caused the injury alleged by the petitioner. After

such determination is made the action can proceed against a manufacturer, distributor, dispenser, or health care provider.

- Process for Determination
  - Any person can petition the Secretary to investigate claims against a manufacturer, distributor, dispenser, or health care provider.
  - Prior to the Secretary's making a determination the manufacturer, distributor, dispenser, or health care provider must be notified and has a right to a formal hearing.
  - Judicial review of the determination may be had at a U.S. Court of Appeals. The review is on the record and the determination is stayed during the proceeding. The courts review shall conform to the procedures for judicial review of administrative orders.

- Designation
  - In a declaration of a public health emergency under319A, the Secretary identifies the pandemic, epidemic, or agent or toxin that presents a public health emergency and designates the products to address such threat.

- Definitions
  - Health Care Provider – includes persons who prescribe, dispense, administer, or provide a facility (e.g., hospital or school) to administer a security countermeasure or pandemic or epidemic product.
  - Non-federal government customers –means a customer of a manufacturer that is a private entity, a health care provider or an individual.
  - Qualified Pandemic or Epidemic Product –means a drug, biologic or medical device developed to diagnose, mitigate, prevent, treat or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause or a serious or life-threatening disease or condition caused by such product. The product must be approved or licensed by the FDA; must have sufficient clinical data to be approved or licensed in eight years; or is authorized by the Secretary for emergency use.
  - Security Countermeasure – a product as defined in section 319F-2(c)(1)(B).